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Food and Drug Administration
Nashville District Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES

297 Plus Park Boulevard
Nashville, TN 37217

October 7, 1997

CERTIFIED-RETURN RECEIPT REQUESTED

Kenny E. Smith, M.D.
Program Sponsor
c/o Gadsden Treatment Center, Inc.
1107 W. Meighan Boulevard
Gadsden, AL 35901

WARNING LETTER - 98-NSV-03

Dear Dr. Smith:

On May 28-29, 1997, Food and Drug Administration (FDA) Investigator Patricia S. Smith inspected your methadone maintenance center, Shoals Treatment Center, Inc., located at 520 Louis Avenue, Muscle Shoals, AL 35661.

Our review and evaluation of the investigator's report of that inspection revealed the following significant violations of the Narcotic Treatment Program Standards, Title 21, Code of Federal Regulations, Part 291.505, Conditions for the Use of Narcotic Drugs:

- Failure of the authorized physician to date and sign or review and countersign findings from the admissions medical evaluations. Of 15 patient files reviewed, only one contained documentation of physician review. [21 CFR 291.505(d)(3)(ii)]

- Failure to perform adequate drug screening tests on prospective patients prior to admittance and dosing with methadone. [21 CFR 291.505(d)(2)(i) and 21 CFR 291.505(d)(4)(ii)(B)]

- Failure to perform medical evaluation on at least one patient until the patient had been receiving doses of methadone for over 30 days and no records of a previous physical exam were obtained from the transferring clinic. [21 CFR 291.505(d)(4)(ii)(B)]

- Serological tests for syphilis were not performed as part of the admission physical for two patients and a third patient began dosing with methadone approximately 60 days before the test was completed. Further, one patient was admitted and began dosing with methadone approximately 30 days prior to completion of a tuberculin skin test. [21 CFR 291.505(d)(3)(i)]

- Failure to obtain FDA approval for each phase advancement involving medication take-home requirements in at least five (5) instances. [21 CFR 291.505(d)(6)(v)]

- At least one patient treatment plan failed to include the names of medications and the reason for providing them for emotional and/or physical problems. [21 CFR 291.505(d)(3)(v)(C)]

The above noted violations and the observations listed on the FDA Form 483 are not intended to be all-inclusive. It is your responsibility as program sponsor to ensure that your program remains in compliance with all federal and state laws and regulations.

Failure to effectively and promptly correct the noted violations, or further violations of the requirements set forth in 21 CFR 291 may result in enforcement action without further notice.

Please direct any correspondence regarding the subject inspection, this letter, and changes you intend to make to the attention of Frank J. Jancarek, Compliance Officer, at the above letterhead address.

Sincerely,

Raymond K. Hedblad

Raymond K. Hedblad
Director, Nashville District

RKH/kl

cc: Stephen A. Nippert
The Tuscaloosa Treatment Center, Inc.
535 River Road, Suite G-3
Tuscaloosa, AL 35404

cc: David F. Burke, M.D.
Shoals Medical Building
P. O. Box 3449
Muscle Shoals, AL 35662

cc: O'Neill Pollingue, Director
Substance Abuse Services Division
Dept. of Mental Health/MR
200 N. Unikon Street, P. O. Box 301410
Montgomery, AL 36130-1410

cc: Attn: Linda Traub
DEA
900 Western America Circle
Suite 501
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